VNUS™

Radio Frequency Generator
RFG*PLUS* Model RFG2 Operator's Manual

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Introduction

Prior to using the RF Generator, review the warnings and cautions in this manual for important safety information.

The VNUS Radiofrequency Generator (RFG*PLUS*) is a product of VNUS Medical Technologies, Inc. It is designed to provide controlled delivery of radiofrequency (RF) energy to RF Devices (e.g., catheters) marketed by VNUS.

The term "Device," used throughout this manual, refers to compatible VNUS RF Devices that can be attached to the RF Generator.

Please refer to the Instructions for Use included with the RF Device for information related to the Device such as clinical procedures, cautions, warnings, precautions, potential complications, and contraindications.

Intended Use

The VNUS RF Generator model RFG2 is intended for use with radiofrequency devices intended for vessel and tissue coagulation.

The RF Generator measures and displays RF output Power, load Impedance (Closure*RFS* only), and elapsed time of RF delivery. The RF Generator also interfaces with a sensor in the Device to provide a continuous display of measured Temperature during RF delivery.

General Safety Guidelines

The safe and effective use of RF energy is highly dependent on factors under the operator's control. There is no substitute for properly trained staff. It is important to read, understand, and follow these directions.

The RF Generator is classified as an electrosurgical product. It must be operated in accordance with the safety guidelines described in this section to ensure a safe environment and safe delivery of RF energy to the patient or to the Device. Failure to adhere to these safety guidelines might result in damage to the RF Generator and/or injury to the patient.

The RF Generator is for prescription use only. It is intended for use only by trained clinicians (operators) in a hospital or clinical environment.

Caution: US federal law restricts this device to sale by or on the order of a physician.

The RF Generator contains no operator-serviceable parts. The RF Generator must be either returned to the factory or repaired by qualified service personnel.

Precautions/Operation Warnings and Cautions

Before operating the RF Generator, review and adhere to these guidelines:

- Do not use the RF Generator if the AC Power cord is damaged.
- Inspect all cords and cables regularly for wear or damage. Discontinue use and discard if damaged.
- Do not use 3–to–2 prong grounding adapters.
- Always use an AC Power center-tap configuration for 240V systems in the U.S.
- Do not operate the RF Generator in contact with flammable materials, chemicals, or substances.
- Protect the RF Generator from exposure to extreme moisture, such as rain.
- Verify that the RF Generator's vent opening, located at the bottom of the unit, is not obstructed. Covering the speaker opening might prevent the operator from detecting auditory tones.
- Do not remove the cover of the RF Generator. There is a potential for electrical shock.
- Always refer to authorized personnel for service.
- An RF Generator failure could result in an unwanted increase in RF Power.

WARNING: The RF Generator produces high voltages on the Device.

RF Treatment Warnings and Cautions

Before performing RF Treatment, review and adhere to these guidelines:

- DANGER, EXPLOSION HAZARD: Do not use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.
- Use the VNUS RF Generator only with VNUS Closure*FAST* or Closure*RFS*. DO NOT use with Devices from any other manufacturer with the RFG2 as this may increase the possibility of increased emissions or decreased immunity.
- Avoid contact of cords and cables with patient, leads, or other equipment.
- Do not wrap the Device cable around metal objects, as this might induce hazardous currents into the patient.
- Be alert for potential interference with pacemakers and other active implants.
- To prevent patient injury, always check to determine if the measured Temperature, Impedance (not displayed for Closure*FAST*), and RF Power shown in the Data Display area are within safe ranges.
- While using the RF Generator during a procedure, do not allow the patient to come into direct contact with grounded metal objects.
- When the RF Generator is activated, the conducted and radiated electrical fields might interfere with other medical electrical equipment. Refer to the "Electromagnetic Interference (EMI)" section of this manual for more information.
- Do not activate RF Power until the Device is properly positioned in the patient.
- RF Power activation tones and lights are important safety features. Do not obstruct lights. Do not disable auditory tones.

Environmental Conditions

Transportation and Storage

During transportation and storage, adhere to these guidelines:

- Store the RF Generator at temperatures between –20°C and 70°C and in non-condensing relative humidity ≤ 90%.
- Do not stack items on top of the RF Generator.
- When the RF Generator is not in use, unplug the unit from the AC Power outlet and wrap the cord around the AC Power cord wrap area.
- Do not carry or lift the RF Generator by the AC Power cord.
- The chemicals from a broken LCD screen are toxic when ingested; handle with care, especially if the LCD screen is broken. If chemicals from a broken LCD screen are accidentally ingested, obtain medical attention immediately.

Operation

Conditions for operating the RF Generator include the following:

- Temperature between 10°C and 40°C
- Relative humidity (non-condensing) between 0% and 90%

Caution: After removing the RF Generator from a storage environment, allow the unit to fully acclimate to the new environment before turning on the unit. Operate the RF Generator only at temperatures between 10°C and 40°C. Operate the RF Generator only in non-condensing humidity conditions.

Unpacking and Inspection of Components

Upon receiving the RF Generator, carefully unpack and inspect the items listed below:

- RF Generator without physical damage to the front or back panels, cover, or screen
- Approved hospital-grade AC Power cord without cracks, frays, or any visible cord or plug damage
- CD-ROM containing this Operator's Manual and the Service Manual

All damaged items must be repacked and returned to VNUS Customer Service Department with prior approval. See the back of this manual for contact information.

Setup and Installation

The RF Generator must be installed and put into service according to the guidance provided in this document to ensure its electromagnetic compatibility. If in doubt, consult VNUS Customer Service or a local distributor.

The RF Generator should be used only with a Hospital Grade power cord and plugged into only grounded, Hospital Grade AC sources.

The VNUS RF Generator can be placed on any stable cart, table, or platform. It is recommended that the cart have conductive wheels and be rated to hold at least 11.5 kg (25 lbs.). Refer to facility protocols and local ordinances for more information.

Provide at least 10 to 15 cm (4–6 in.) of space around the sides and top of the RF Generator for air circulation and cooling. After continuous use for extended periods of time, it is normal for the top and rear panel to be warm. Do not block vent openings.

Warning: Do not stack any items on top of the RF Generator. Doing so could damage the unit. The RF Generator should not be used adjacent to other equipment. If adjacent or stacked use is necessary, the RF Generator should be observed to verify normal operation in the configuration in which it will be used.

Mechanical Specifications

- Size: 38 cm x 38 cm x 19 cm (15 in. x 15 in. x 7.5 in.) maximum
- Weight: 9 kg (20 lbs.) maximum

Equipment Type

The Class I RF Generator is designed to work with Type CF, Defibrillator-Proof RF Devices. The RF Generator is designed to withstand an application of an external defibrillator while the RF Device is in use.

Equipment Description

Labeling Symbols

There are several symbols and icons used throughout this manual that are used by the RF Generator and its displays. The operator should be familiar with these symbols and their meanings.

Table 1: Data Display Area Symbols and Icons

Ω	Ohms (Impedance)		Information, Question, or Verification
°C	Degrees Celsius (Temperature)		Warning: Consult alarm/advisory message
W	Watts (Power)		Data Logging Indicator
OR	ClosureFAST icon: RF not actively powered	OR	ClosureFAST icon: RF actively powered to cause tissue heating

Table 2: RF Generator Symbols and Icons

I	AC Power ON		Non-Ionizing Radiation
O	AC Power OFF		Earth Ground
	RF Power ON	MMC Card	MultiMediaCard (MMC) Slot
	RF Power OFF		Increment/UP
	Attention: Consult accompanying documents		Decrement/DOWN
	Fuses		Patient Isolated
	Alternating Current		Electrostatic Sensitive Device (referring to MMC card)

Visual Indicators

The RF Generator includes the following visual indicators, as depicted in Figure 1:

- **AC Power:** Indicates when the RF Generator is turned on.
- **RF Power:** Indicates RF Power status by changing color and illumination, as listed in Table 3.

Table 3: RF Power Button Status

Light	Color	Status	Mode
OFF	None	RF Power is disabled.	Identification or Measure
ON	Green	RF Power is enabled (ready for use).	Measure
ON	Flashing Green	RF Power is enabled, ready for a catheter or button press to activate RF treatment	Ready
ON	White	RF Power is activated (in use) and currently delivering RF Power.	RF Treatment

Treatment RF Power cannot be enabled until a Device is connected.

Audible Indicators

The RF Generator has several audible indicators designed to alert the operator:

- **Alarm:** Set of three rapid, high-frequency tones. Sound pressure level of alarm tones is
  > 45dB (procedural tone volume at quietest setting) and
  > 80dB (procedural tone volume at loudest setting).
- **Informational:** Single short, low-frequency tone
- **Invalid:** Single short, low-frequency tone
- **Power On:** Three ascending-scale tones
- **RF Power On – Treatment**: Two descending-scale tones
- **RF Power On – Alert**: Two rapid groups of two high-frequency tones
- **RF Start**: Single, long low-frequency tone
- **RF Stop:** Single, long low-frequency tone
- **Valid:** Single short, high-frequency tone

Each button press produces a valid or invalid tone. If a button fails to sound, this indicates button malfunction. Should a button malfunction, have the unit serviced.

Front Panel

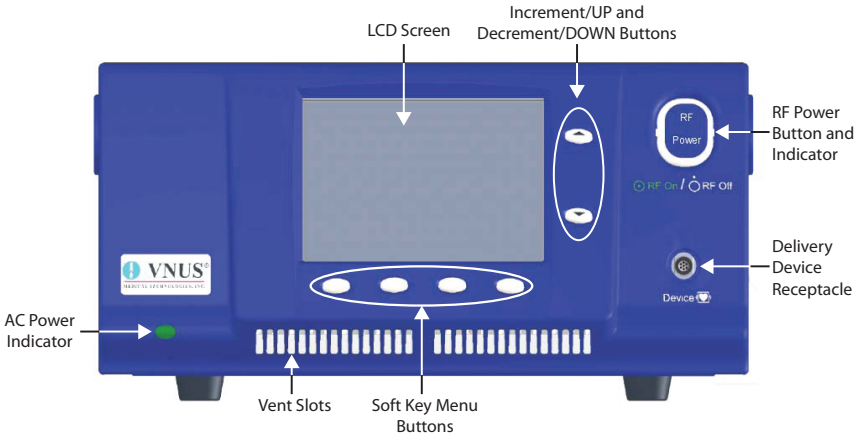

Figure 1: Front Panel

The RF Generator includes the following buttons on its front panel, as depicted in Figure 1:

- Soft Key Menu: Activate the Soft Key Menus displayed directly above the buttons on the LCD display.
- Increment/UP (▲) and Decrement/DOWN (▼): Cycle up or down through the available menu choices. After selecting a choice, press these buttons to increase, decrease, or toggle the value of that choice.
- RF Power: Activates or deactivates RF Power.

Rear Panel

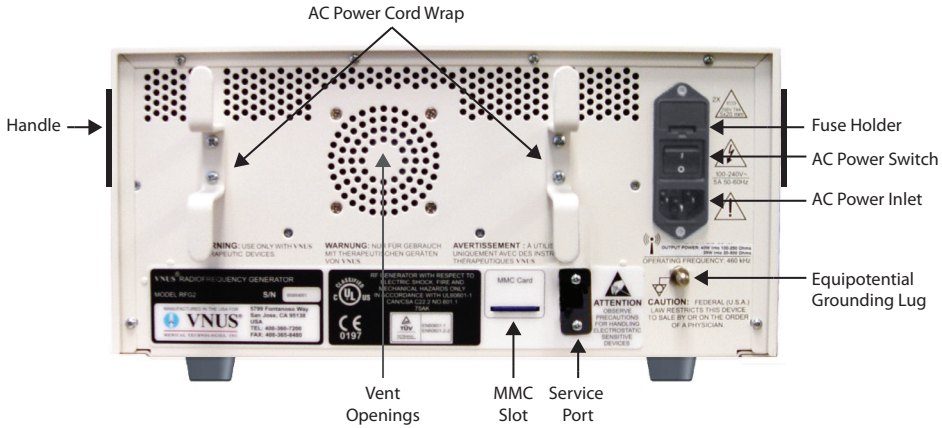

Figure 2: Rear Panel

The RF Generator includes these features, as depicted in Figure 2:

- **AC Power Switch:** Turns on or off the RF Generator's AC Power.
- **AC Power Cord Wrap:** When the RF Generator is not in use, unplug the unit from the AC Power source and wrap the cord around the AC Power cord wrap area.
- **AC Power Inlet:** Connects the AC Power cord to the RF Generator.
- **Equipotential Grounding Lug:** Provides a point for an auxiliary Earth Ground connection.
- **Fuse Holder:** Includes two 4A/250V, slo-blo, 5x20 mm fuses.
- **Handle:** The RF Generator has a handle on each side. Use these handles while carrying or lifting the unit.
- **MultiMediaCard (MMC) Slot:** Accepts a MultiMediaCard that can be used to store procedure data and to perform software upgrades.
- **Service Port:** The RF Generator includes a port that is used for calibration and repairs. This port is for use by qualified service personnel only.
- **Vent Openings:** The RF Generator includes vent openings on the rear panel. Do not block these openings.

LCD Screen – Closure*FAST*

The LCD screen consists of three areas: the Data Display area, Operator Message area, and Soft Key Menu area.

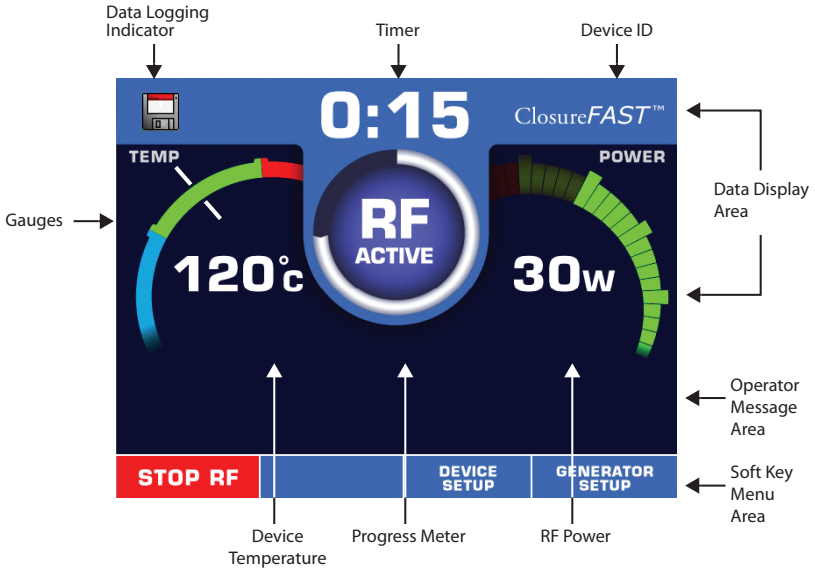

Figure 3: Closure*FAST* Main Screen

The Data Display area displays information about the RF Generator's status. Depending on the status of the RF Generator, information in this area changes to show the following items:

- **Data Logging Indicator:** Indicates that a MultiMediaCard has been inserted and data is being logged.
- **Device ID:** Indicates type of Device connected to the RF Generator.
- **Device Temperature:** Indicates current Temperature of connected Device.
- **Gauges:** Indicates Temperature and RF Power with an acceptable range shown for Temperature.
- **Progress Meter:** Indicates treatment time remaining
- **Timer:** The timer counts down starting from the selected treatment time.
- **RF Power:** Indicates current RF Power delivered to the Device.

LCD Screen – Closure*RFS*

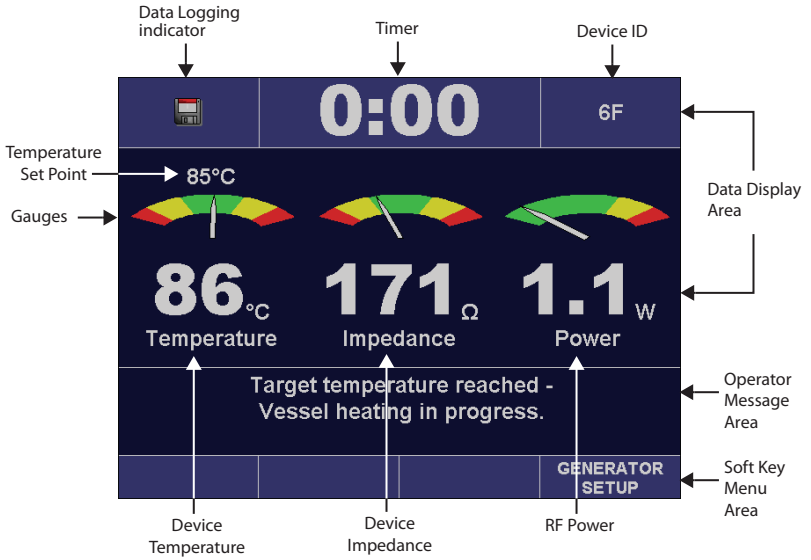

Figure 4: Closure*RFS* Main Screen

The Data Display area displays information about the RF Generator's status. Depending on the status of the RF Generator, information in this area changes to show the following items:

- **Data Logging Indicator:** Indicates that a MultiMediaCard has been inserted and data is being logged.
- **Device ID:** Indicates type of Device connected to the RF Generator.
- **Device Impedance:** Indicates current Impedance of connected Device
- **Device Temperature:** Indicates current Temperature of connected Device; it is not intended to measure patient body temperature.
- **Gauges:** Indicates whether Temperature, Impedance, and RF Power are within or outside of preset limits.
- **Timer:** Indicates the amount of time RF Power has been delivered during the current RF Power On cycle.
- **RF Power:** Indicates current RF Power delivered through the Device.

Gauges – Closure*FAST*

The RF Generator's Data Display area includes colored gauges when a Device is connected. These gauges provide a quick and easy way to determine if the Device's parameters (Temperature and RF Power) are within acceptable ranges. If a parameter is not within an expected range, the RF Generator displays an advisory message and sounds a tone.

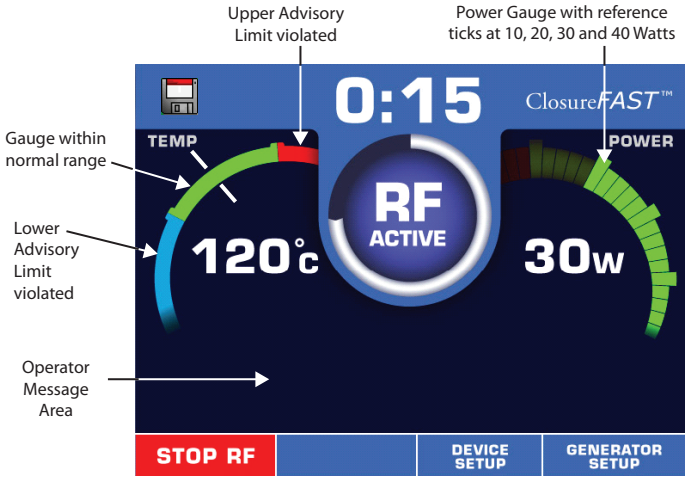

Figure 5: Closure*FAST* Data Display with Gauges

The position of the Temperature gauge's needle is based on the current value. It points to one of three colored areas, as described below:

Green: Within normal range

Red: Temperature above Advisory Limit

Blue: Temperature below Advisory Limit

The extent of illumination of the Power gauge is based on the current Power value.

Green: Within normal range

Red: Power above Advisory Limit

For more information about these Limits, see the "Functional and Advisory Limits" section of this manual.

Gauges – Closure*RFS*

The RF Generator's Data Display area includes colored gauges when a Device is connected and not in Measure Mode. These gauges provide a quick and easy way to determine if the Device's parameters (Temperature, Impedance, and RF Power) are within acceptable ranges. If a parameter is not within an expected range, the RF Generator displays an advisory message and sounds a tone.

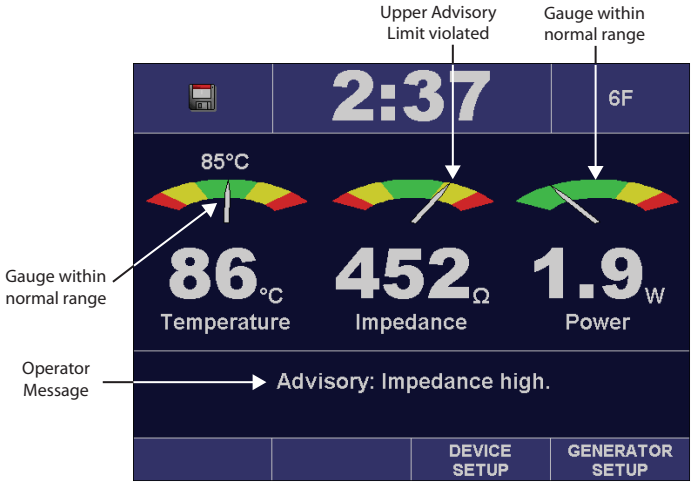

Figure 6: Closure*RFS* Data Display with Gauges

The position of the gauge's needle is based on the current value of the corresponding parameter (Temperature, Impedance, or RF Power). It points to one of three colored areas, as described below:

- **Green**: Within normal range
- **Yellow:** Violation of Advisory Limits
- **Red:** Violation of Functional Limits

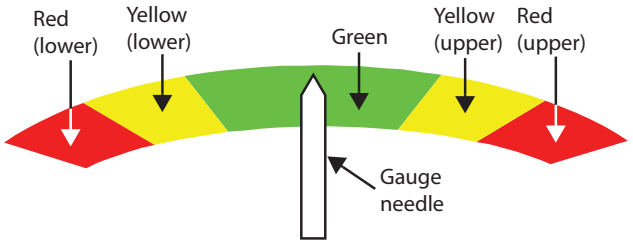

Figure 7: Gauge

For more information about these Limits, see the "Functional and Advisory Limits" section of this manual.

Instructions for Use

To ensure safe RF delivery, it is important to be familiar with how the RF Generator works, how to change desired settings, and how to interpret displays.

AC Power

The VNUS RF Generator includes an approved hospital-grade AC Power cord.

Prior to each use, inspect the AC Power cord, the AC Power inlet, and the AC Power outlet that the unit plugs into.

To turn on the RF Generator:

1. Plug the AC Power cord into the AC Power inlet at the back of the unit.
2. Plug the AC Power cord into a grounded hospital-grade AC Power outlet.
3. Press the AC Power switch UP to turn on the unit.
4. Verify the AC Power indicator is lit when the unit turns on.

   If the indicator is not lit, check the AC Power cord, fuses, and AC Power outlet.
5. Verify all pixels on the unit's LCD screen illuminate white when turning on the unit.

Caution: Do not plug the RF Generator into the AC Power outlet if any of its surfaces appear to be cracked or damaged. Do not use the RF Generator if the AC Power cord is damaged. Do not use extension cords and/or adapter plugs.

Changing Settings

The RF Generator lets the operator change the values of Device and RF Generator settings. The operator should be familiar with how to change setting values:

1. Use the **Soft Key Menu** buttons located below the Data Display area to choose the **DEVICE SETUP** or **RFG SETUP** Soft Key Menu.

   The Operator Message area displays a sub-menu of settings.

   The Soft Key Menu area displays related Soft Key Menus:

   - **DEFAULTS:** Returns all settings to the RF Generator's factory defaults (except for Date, Time, and Language settings).
   - **SELECT:** Indicates the options for the highlighted setting.
   - **EXIT:** Returns to the previous screen.
2. Use the **Increment/UP** (▲) and **Decrement/DOWN** (▼) buttons to highlight a setting.
3. Press the **SELECT** Soft Key Menu button to select the highlighted setting.

   The Operator Message area indicates the value(s) for the highlighted setting.

The Soft Key Menu area displays related Soft Key Menus:

- **DEFAULT**: Restores the selected setting to the factory default value (except for Date, Time, and Language settings).
- **ACCEPT**: Saves the setting's value(s) as the default value(s).
- **CANCEL**: Cancels the selection and returns to the previous screen.

4. Use the **Increment/UP** (▲) and **Decrement/DOWN** (▼) buttons to increment, decrement, or toggle the value(s) of the selected setting.
5. Press the **ACCEPT** Soft Key Menu button to save the choice as a default setting or press the **CANCEL** Soft Key Menu button to return to the previous screen without saving any changes.
6. After changing the desired setting(s), press the **EXIT** Soft Key Menu button to return to the RF Generator screen.

Connecting a Device

To connect a Device, insert the Device's connector into the receptacle on the RF Generator. If the unit is turned on before a Device is attached, the RF Generator prompts the operator to connect a Device.

Notice the small red dot at the top of the Device receptacle. This dot must be lined up with the small red mark and/or raised line on the Device connector being connected to the RF Generator.

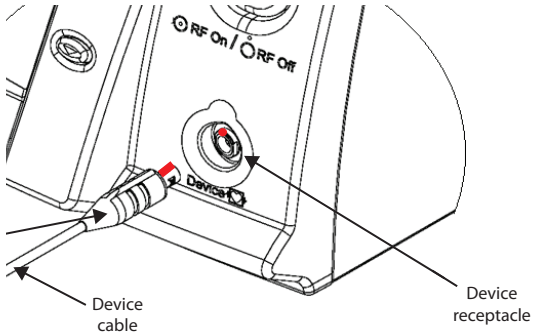

Figure 8: Connecting a Device

When a Device is connected, the RF Generator's LCD screen displays RF Treatment information, as shown in Figures 9 and 10.

Measure Mode

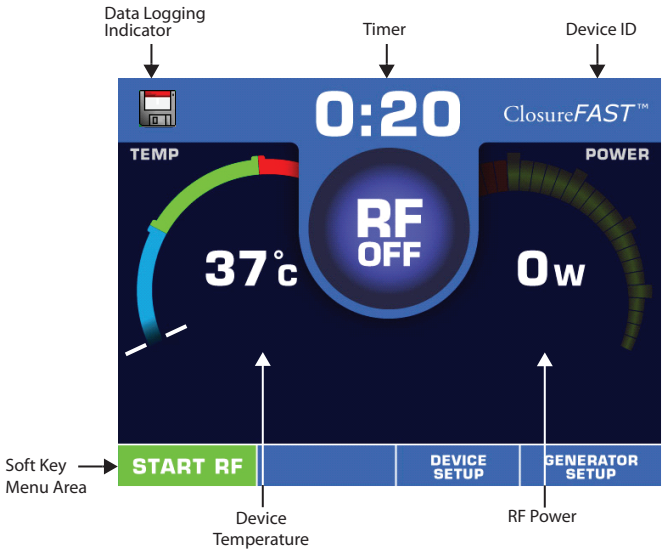

Figure 9: Closure*FAST* Measure Mode

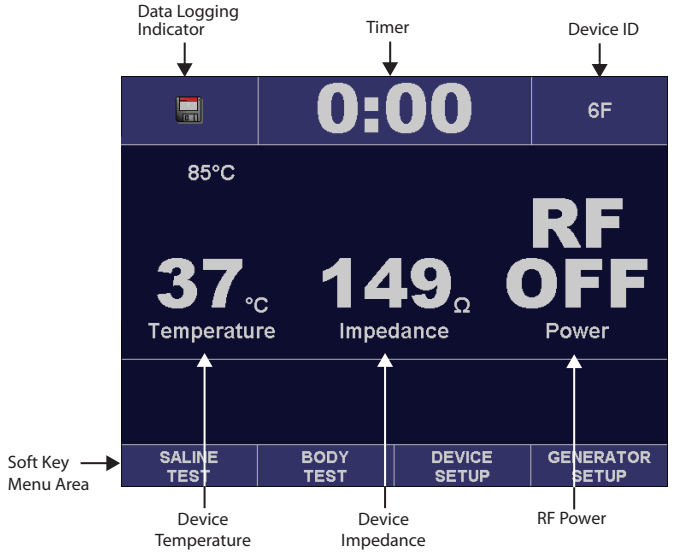

Figure 10: Closure*RFS* Measure Mode

RF Treatment - Closure*FAST*

WARNING: Review this section and the "General Safety Guidelines" section of this manual before starting RF Treatment.

Before starting RF Treatment, review the Device's Instructions For Use. Confirm that the connected Device matches the Device ID shown in the Data Display area.

Entering Ready Mode

Press the **RF Power** button to enter Ready Mode. The RF Power button will change from non-illuminated to flashing green illumination.

Initiating RF Treatment

Press the **START RF** button or the Device handle button to start RF Treatment. While delivering RF Power, the **RF Power** button illuminates white. The Device will increase to the set temperature and hold at that temperature until the treatment time has completed. After the treatment time has counted down to zero, RF Power delivery will stop automatically and the **RF Power** button will change to flashing green illumination to indicate **Ready** Mode. Pressing the **START RF** button or the Device handle button will start the next RF Treatment.

WARNING: Do not activate RF Power until the Device is properly positioned in the patient. Refer to the "General Safety Guidelines" section of this manual before starting RF Treatment.

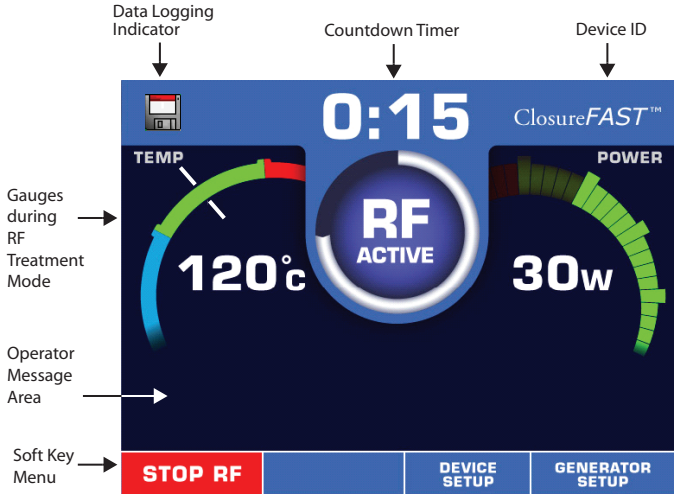

Figure 11: Closure*FAST* RF Treatment Started

Temperature and Impedance must be within Functional Limits before RF Treatment can start. This temperature display is not intended to measure patient temperature but reflects Device temperature within a relative range.

Halting RF Treatment

During RF Delivery, press the **STOP RF** button or the Device handle button to halt RF Treatment (pressing the **RF Power** button will also halt RF Treatment and disable Ready mode).

RF Treatment halts automatically if:

- The time set for RF Treatment has elapsed (for Devices where RF Treatment time can be set).
- A Functional Limit has been violated.
- The RF Generator detects an error.
- The Device is disconnected.

WARNING: If RF Treatment does not halt automatically, disconnect the Device.

Restarting RF Treatment

The operator should correct any alarm condition before restarting RF Treatment. (See the "RF Treatment Difficulties" section of this manual for more information.)

If the operator unplugs a Device and then reconnects a Device of the same model, the unit prompts the operator to either retain or discard the Timer Value. Press the **YES** or **NO** Soft Key Menu button to retain or discard, respectively, the sum of all times from all previous RF Power On cycles.

If the unit has been turned off, a new Timer Value will start with the time reset to zero (0:00) when the unit is turned on again.

The Total Treatment Time displays in the Operator Message area immediately after RF Power halts.

RF Treatment - Closure*RFS*

WARNING: Review this section and the "General Safety Guidelines" section of this manual before starting RF Treatment.

Before starting RF Treatment, review the Device's Instructions For Use. Confirm that the connected Device matches the Device ID shown in the Data Display area.

It is also highly recommended that the operator perform the optional Saline and Body Tests. These tests verify the Temperature and Impedance measurements of the Device. For information on performing the Saline Test and Body Test, refer to the "Saline Test Mode" and "Body Test Mode" sections of this manual.

When the RF Generator and connected Device are ready to start RF Treatment, the **RF Power** button illuminates green. This indicates that Temperature and Impedance measurements are within the Functional range for the connected Device, and RF Treatment can start.

Temperature and Impedance must be within Functional Limits before RF Treatment can start.

Initiating RF Treatment

Press the **RF Power** button to start RF Treatment. While delivering RF Power, the **RF Power** button illuminates white. The Device will increase to the set temperature and hold at that temperature until the RF Treatment is halted.

WARNING: Do not activate RF Power until the Device is properly positioned in the patient. Refer to the "General Safety Guidelines" section of this manual before starting RF Treatment.

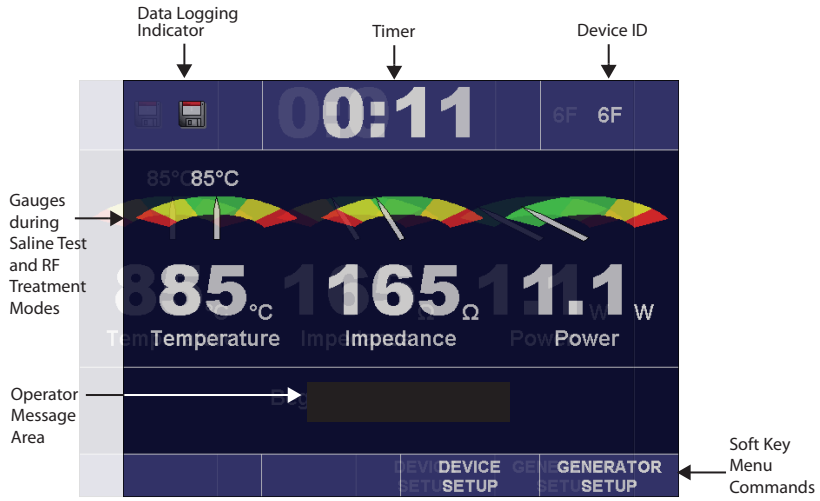

Figure 12: Closure*RFS* RF Treatment Started

Halting RF Treatment

During RF Delivery, press the **RF Power** button to halt RF Treatment.

RF Treatment halts automatically if:

- A Functional Limit has been violated.
- The RF Generator detects an error.
- The Device is disconnected.

Restarting RF Treatment

The operator should correct any alarm condition before restarting RF Treatment. See the "RF Treatment Difficulties" section of this manual for information.

If the operator unplugs a Device and then reconnects a Device of the same model, the unit prompts the operator to either retain or discard the Timer Value. Press the **YES** or **NO** Soft Key Menu button to retain or discard, respectively, the sum of all times from all previous RF Power On cycles.

If the unit has been turned off, a new Timer Value will start with the time reset to zero (0:00) when the unit is turned on again.

The Total Treatment Time displays in the Operator Message area immediately after RF Power halts.

Using MultiMediaCards

MultiMediaCards (MMCs) can store data from recent procedures, log generator errors, and perform software updates. The operator must use VNUS part number MMC.

WARNING: Proper ESD precautionary procedures should be used when handling, inserting, or removing the MMC card.

Before handling the MMC card, touch the metal frame of the RFG2 to discharge any static electricity. Alternatively, you may use an ESD wrist strap to bond yourself to the RFG2 or to earth. This is important to avoid electrostatic discharge damage to the MMC card.

All personnel who handle the MMC card should receive an explanation of the ESD warning symbol and training in ESD precautionary procedures. This includes clinical/biomedical engineering and health-care staff. At minimum, this training should include:

- an introduction to the physics of electrostatic charge
- the voltage levels that can occur in normal practice
- the damage that can be done to electronic components if equipment are touched by an operator who is electrostatically charged
- methods to prevent build-up of electrostatic charge,
- how and why to discharge one's body to earth or to the frame of the RFG2, or bond oneself by means of a wrist strap to the RFG2 or to earth prior to handling the MMC card

Functional and Advisory Limits

While a Device is connected, the RF Generator monitors the Device's parameters (Temperature, Impedance, and RF Power). Parameters must be within Functional Limits before RF Treatment can start. The Limits are determined by predefined settings for the connected Device. Advisory Limits are within the range of Functional Limits.

WARNING: Operation of the RF Generator below these values may cause inaccurate results. The RF Generator will not allow treatment if measurements persist outside of these limits.

The limits can also be affected by Set Points that the operator defines in the Device Setup menu. See the "Device Setup Mode" section of this manual for information about defining Set Points.

Functional Limits

Functional limits for Closure*FAST*:

- Patient Temperature: 10°C to 130°C

Functional limits for Closure*RFS*:

- Patient Temperature: 10°C to 110°C
- Device Impedance in Treatment, Saline, or Body Test Modes: 25-1000 Ω
- Device Impedance in Measure Mode: ≥10 Ω

If the RF Generator detects that a parameter violates Functional Limits, the gauge displays within the red range. The unit also:

- Halts RF Treatment.
- Sounds an Alarm Tone (for Temperature or RF Power parameters) or sounds an Informational Tone (for the Impedance parameter).
- Enters Alarm Acknowledge Mode.
- Displays an Alarm Message.

*Advisory Limits - Closure*FAST

During RF treatment:

- If the set temperature is not reached within a predetermined time, RF power will be stopped before the countdown has completed. This indicates a condition of poor contact between the Device and the tissue to be treated.
- If the RF Generator detects that temperature is below the Advisory Limit, the gauge displays within the blue range. The unit sounds an Informational Tone and displays a message.

*Advisory Limits - Closure*RFS

If the RF Generator detects that a parameter violates Advisory Limits, the gauge displays within the yellow range. The unit sounds an Informational Tone and displays a message.

Operating Modes

The RF Generator has several operating modes. The operator must pay special attention to the Data Display area and Operator Message area during the Body Test, Saline Test, Measure, and RF Treatment modes, in which some level of RF Power is delivered.

Failure during any operating mode results in the RF Generator either not starting RF Treatment or automatically halting RF Treatment.

Power On Self Test (POST) Mode

During the Power On Self Test (POST), the RF Generator performs a number of internal self-tests of its software:

- Verifies integrity of system random access memory (RAM).
- Verifies contents of program read-only memory (ROM).
- Activates all visual indicators, including the LCD screen and the backlit Soft Key Menu buttons around the screen.
- Sounds Power On tone.
- Verifies operation of radiofrequency (RF) generation and measurement circuits.
- Displays a notice if POST must restore the factory default settings due to a corruption of persistent settings, such as screen brightness or tone volume settings.

Prior to using the RF Generator, observe that the screen, lights, and audible alarms cycle.

Caution: The RF Generator enters Error Mode if it detects a failure during the Power On Self Test (POST) Mode. If any error messages occur indicating that the RF Generator is not safe to use, power off the unit and contact VNUS Customer Service.

Identification Mode

During Identification Mode, the RF Generator checks for a connected Device:

- If no Device is connected, the Operator Message area asks the operator to "Please connect device."
- If the connected Device is unsupported, the Operator Message area says, "The connected device is unsupported. Please connect another device."
- If the connected Device is unknown or invalid, the Operator Message area says, "The device is invalid."

The Data Display area displays the current software version and the VNUS logo, as shown in Figure 13.

Data Display Area
VNUS®
MEDICAL TECHNOLOGIES, INC.
RFG2 - VERSION 4.1.0
Please connect device.
Operator Message
GENERATOR SETUP
Press the Soft Key Menu button below a menu command to view or change settings.

Figure 13: Identification Mode

Measure Mode

Measure Mode starts whenever a Device is attached to the RF Generator. During Measure Mode, the Data Display area displays the current parameters for the connected Device.

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*For Closure*FAST*, violating Functional Limits while in Measure Mode results in an advisory message. The operator cannot start RF Treatment if the Device violates Functional Limits.*

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*Caution: For Closure*RFS *the Measure, Saline Test, and Body Test modes use a small amount of RF energy (2.3 mW*RMS*) to measure Impedance at the Device tip. During these modes, output power is insufficient to cause tissue heating. However, the operator should be alert for interference to nearby equipment. For more information about interference, please consult the "Electromagnetic Interference (EMI)" section of this manual.*

Saline Test Mode - Closure*RFS* only

The Saline Test performs Temperature and Impedance measurements using 0.9% saline solution.

When the operator presses the **SALINE TEST** Soft Key Menu button, the Saline Test displays for approximately 10 seconds before timing out. Pressing the button again will restart the test. The Saline Test displays the relationship between:

- The measured Impedance and the expected Impedance range.
- The measured Temperature and the expected Temperature.

Values can vary due to actual saline temperature and should be verified before RF Treatment starts.

Caution: If a Saline Test indicates advisory conditions, this might indicate a faulty Device. Consult the Device's Instructions for Use for more information.

Body Test Mode - Closure*RFS* only

The Body Test performs Temperature and Impedance measurements using the Device positioned in the patient for RF Treatment.

When the operator presses the **BODY TEST** Soft Key Menu button, the Body Test displays for approximately 15 seconds before timing out. Pressing the button again will restart the test. The Body Test displays the relationship between:

- The measured Impedance and the expected Impedance range.
- The measured Temperature and the expected Temperature range.

When the Body Test has completed, the most recent Temperature and Impedance measurements display in the Operator Message area.

Caution: If a Body Test indicates advisory conditions, this might indicate a faulty Device. Consult the Device's Instructions for Use for more information.

Alarm Acknowledge Mode

The Alarm Acknowledge Mode starts when RF Treatment halts due to an alarm or unrecoverable error. See the "RF Treatment Difficulties" section of this manual for information about unrecoverable errors. To end the Alarm Acknowledge Mode, press the **OK** Soft Key Menu button or wait 30 seconds for the mode to complete.

Once the Alarm Acknowledge Mode has completed, the RF Generator enters Measure Mode if a Device is connected or Identification Mode if a Device is not connected.

Ready Mode - Closure*FAST* only

Ready Mode starts after a Closure*FAST* Device is attached to the RF Generator and the **RF Power** button is depressed as prompted on the screen. During Ready Mode, the Data Display area displays the current parameters for the connected Device. During Ready Mode, the RF Generator is enabled and will deliver RF power when the **START RF** button or the Device handle button is pressed.

RF Treatment Mode

During the RF Treatment Mode, the RF Generator delivers RF Power. The RF Treatment Mode becomes active when the following are true:

Closure*Fast*:

- Temperature and Impedance measurements are within Functional range for the connected Device.
- The **RF Power** button has been pressed to enter ready mode.
- The operator presses the **START RF** button or the Device handle button (note that if body temperature has not been measured, an alert will display; this alert can be cleared by pressing **OK** to proceed).

Closure*RFS*:

- The operator presses the **RF Power** button.

When RF Treatment has completed, the RF Generator enters Measure Mode or Alarm Acknowledge Mode. For more information about RF Treatment, read the "RF Treatment" sections of this manual.

Error Mode

Error messages display when the RF Generator encounters an unrecoverable (unable to continue) error.

The Error Mode becomes active and an error code or message displays if any of the following occurs:

- The RF Generator detects an unexpected internal error.
- The Power On Self Test (POST) fails.

When the Error Mode occurs, RF Treatment halts immediately and the RF Generator logs an entry in the Error Log.

When an error message indicates a non-recoverable error has occurred, turn off the unit, wait a few seconds, and then turn on the unit.

If an error persists, make a note of it and then contact VNUS Customer Service or a local distributor.

RFG Setup Mode

The RFG Setup menu provides a list of settings for the RF Generator. When the operator presses the **RFG SETUP** Soft Key Menu button, the Operator Message area displays the settings available for the RF Generator.

To change a setting's value(s):

1. Press the **RFG SETUP** Soft Key Menu button to display the RFG Setup settings.
2. Use the **Increment/UP** (▲) and **Decrement/DOWN** (▼) button to highlight a setting.
3. Press the **SELECT** Soft Key Menu button to select the highlighted setting.
4. Use the **Increment/UP** (▲) and **Decrement/DOWN** (▼) button to cycle through the values until the desired value displays.
5. Press the **ACCEPT** Soft Key Menu button to accept the change.
6. Press the **EXIT** Soft Key Menu button to return to the RF Generator screen.

Proc Tone Vol

The Proc Tone Vol setting adjusts the Procedural Tone Volume from 2 (quietest) to 10 (loudest) The Procedural Tone Volume controls the volume of alarm tones and tones associated with RF Power delivery, such as RF Power start and stop tones. When the volume setting is increased or decreased, a single tone sounds to denote the change.

The operator is prevented from adjusting the Procedural Tone Volume to be quieter than the Informational Tone Volume. If the operator adjusts the Procedural Tone Volume to be equal to or less than the Informational Tone Volume, the Informational Tone Volume automatically adjusts to one level lower than the Procedural Tone Volume.

Info Tone Vol

The Info Tone Vol setting adjusts the Informational Tone Volume from 1 (quietest) to 9 (loudest). The Informational Tone Volume controls the volume of button acknowledgement tones and informational tones. When the volume setting is increased or decreased, a single tone sounds to denote the change.

*Gauges - Closure**RFS** only*

The Gauges setting adjusts the Parameter Range Indication gauges as either ON or OFF.

Brightness

The Brightness setting adjusts screen Brightness from 1 (dimmest) to 10 (brightest).

Language

The Language setting selects the Language displayed on the RF Generator's screen. The default language is English.

The operator can change the default language from the RFG Setup Mode. The operator can also change the language during the Power On Self Test (POST) Mode:

1. Press the AC Power switch UP to turn on the unit.
2. When the Power On Self Test (POST) starts, simultaneously press the first two (starting at left) Soft Key Menu buttons.
3. Change the setting's value using the Soft Key Menu buttons and the **Increment/UP** (▲) and **Decrement/DOWN** (▼) buttons.

Date

The Date setting adjusts the current Date.

Time

The Time setting adjusts the current Time.

Device Setup Mode

The Device Setup menu provides a list of settings for the connected Device. When the operator presses the **DEVICE SETUP** Soft Key Menu button, the Operator Message area displays settings for the connected Device.

To change a setting's value(s):

1. Press the **DEVICE SETUP** Soft Key Menu button to display the Device Setup settings.
2. Use the **Increment/UP** (▲) and **Decrement/DOWN** (▼) button to highlight a setting.
3. Press the **SELECT** Soft Key Menu button to select the highlighted setting.
4. Use the **Increment/UP** (▲) and **Decrement/DOWN** (▼)button to cycle through the values until the desired value displays.
5. Press the **ACCEPT** Soft Key Menu button to accept the change.
6. Press the **EXIT** Soft Key Menu button to return to the RF Generator screen.

Settings

Device Setup settings differ, depending on which Device the operator connects. The Device determines the maximum and minimum values allowed for each setting. Available settings include:

- **Phase (1 or 2):** Closure*FAST* only. Adjusts the RF Treatment time (in seconds). Note that there are two phased settings to allow a higher maximum power during initial heating followed by a lower power to maintain temperature. Total treatment time is the sum of the Phase 1 and Phase 2 values, after which treatment will stop automatically.
- **Maximum Power (W):** Adjusts the maximum RF Power (in Watts).
- **Temperature (°C):** Adjusts the desired target Temperature.
- **RFS Advisory Interval (s):** Closure*RFS* only. Adjusts the time between advisory tones.

Maintenance

Cleaning and Disinfection

Caution: Always unplug the AC Power cord prior to cleaning the RF Generator.
Avoid spilling liquids into the RF Generator during cleaning.
Avoid getting cleaning materials inside Device receptacle.

The RF Generator requires no scheduled maintenance other than cleaning external surfaces. It is recommended that the operator clean the unit prior to each use or as needed.

The recommended agents for cleaning RF Generator surfaces (not including the LCD screen) to prevent surface degrading or discoloration include the following:

- Five percent solution of household bleach (approximately 2,500 ppm Sodium Hypochlorite)
- Sporicidin®
- IPA 70/30

The recommended agent for cleaning the transparent, protective cover of the LCD screen is IPA 70/30.

RF Generator cannot be sterilized and must not enter a sterile surgical field.

Disposal

Follow local governing ordinances and recycling plans regarding disposal or recycling of components.

WARNING: The RF Generator includes a lithium battery. The battery holder inside the RF Generator is marked with the symbol at left.

Do not incinerate or dispose of lithium batteries in general trash collection.

Check state and local regulations dealing with the disposal of these materials.

Troubleshooting

Technical Assistance

To obtain technical assistance, contact VNUS Customer Service or a local distributor. See the back of this manual for contact information.

Error Codes

If an error occurs, the RF Generator displays an error code. An error will be one of two types: unrecoverable or recoverable:

- **Unrecoverable errors** halt the RF Generator and require the operator to reset the RF Generator's AC Power to continue. If an unrecoverable error occurs, turn off the unit, wait a few seconds, and then turn on the unit. If the problem persists, contact VNUS Customer Service or a local distributor.
- **Recoverable errors** require the operator to respond to an error message or make a clinical decision.

See Service Manual for a list of errors.

RF Treatment Difficulties

During RF Treatment, the RF Generator monitors the Device's parameters (Temperature, Impedance, and RF Power). Should Temperature, Impedance, or RF Power become too high or too low, as indicated by its gauge, the RF Generator may halt RF Treatment, sound an alarm, and display an alarm message (Impedance is not displayed for Closure***FAST***).

Tables 4 and 5 provide general recommendations for some situations that the operator might encounter. They do not include every possible situation that might occur. For more information, please refer to the Device's Instructions for Use.

Table 4: RF Treatment Difficulties – Closure*FAST*

Closure*FAST* Difficulty	Possible Cause	Corrective Action
Unable to activate RF Power	Temperature and/or Impedance parameter outside Functional Limits	Check Temperature value; adjust as necessary to bring parameters into Functional range.
	Ready Mode not entered	Press the non-illuminated **RF Power** button and observe that it flashes on and off to indicate the RF generator is in ready Mode. Then, activate RF Power when ready.
	Body temperature not measured	Verify that the Device has been inserted into the body and is properly positioned to begin treatment. Press **OK** to proceed and then press the **START RF** button or the Device handle button to activate RF Power.
	Connected device is broken	Check the Device connector to verify that it is plugged in properly. Replace Device.
Power high	Inadequate vessel exsanguination	Verify that the Device is properly positioned. Check for flow, and employ or improve compression techniques as necessary.
Temperature low	Inadequate vessel exsanguination	Verify that the Device is properly positioned. Check for flow, and employ or improve compression techniques as necessary.
	Temperature Set Point is set too low	Check and adjust Temperature Set Point.
	Saline in Device connector	Check for presence of saline. If present, contact VNUS Customer Service. (Note: Take care never to plug a wet Device connector into the receptacle, as this may damage the RF Generator).
	Device, cable, or connector is damaged	Check all connections, cable, and the Device for visible damage. Replace Device.
	Temperature decreases as power is applied	Replace Device.
Temperature high	Saline in Device connector	Check for presence of saline. If present, contact VNUS Customer Service. (Note: Take care never to plug a wet Device connector into the receptacle, as this may damage the RF generator).
	Temperature Set Point is set too high	Check Temperature Set Point.
Non-uniform temperature	Uneven compression across full length of heating element	Note Device position with shaft markers. Check Device and replace if damaged. If not damaged, insert Device to desired location, Verify that the Device is properly positioned. Employ or improve compression techniques as necessary. Press the **START RF** button or the Device handle button to activate RF Power.

Closure*FAST* Difficulty	Possible Cause	Corrective Action
Impedance low (not displayed)	Saline in Device connector and/or receptacle	Check for presence of saline. If present, contact VNUS Customer Service. (Note: Take care never to plug a wet Device connector into the receptacle, as this may damage the RF Generator.) If saline is not present in Device connector or receptacle, perform a Saline Test to verify functionality of Device. Replace Device or instrument cable if Saline Test Impedance values are out of range.
	Short circuit	Replace Device.
Impedance high (not displayed)	Open circuit	Check Device connection (disconnect and then re-connect).

Table 5: RF Treatment Difficulties - Closure*RFS*

Closure*RFS* Difficulty	Possible Cause	Corrective Action
Impedance low	Inadequate electrode-vein wall contact	Improve or employ vein compression techniques.
	Saline in Device connector and/or receptacle	Check for presence of saline. If present, contact VNUS Customer Service. (Note: Take care never to plug a wet Device connector into the receptacle, as this may damage the RF Generator.) If saline is not present in Device connector or receptacle, perform a Saline Test to verify functionality of Device. Replace Device or instrument cable if Saline Test Impedance values are out of range.
	Short circuit	Replace Device.
Impedance high	Coagulum formation on electrodes	Check Device tip for coagulum and remove as required.
	Device not in contact with target tissue	Verify that Device is properly positioned.
	Open circuit	Check Device connection (disconnect and then re-connect).
Power high	Too much blood flow Pullback rate too fast	Check and improve exsanguination. Verify proper pullback rate.

Closure*RFS* Difficulty	Possible Cause	Corrective Action
Temperature low	Inadequate vessel exsanguination	Verify that the Device is properly positioned. Check for flow, and employ or improve compression techniques as necessary.
	Pullback rate too fast	Verify proper pullback rate.
	Temperature Set Point is set too low	Check and adjust Temperature Set Point.
	Saline in Device connector	Check for presence of saline. If present, contact VNUS Customer Service. (Note: Take care never to plug a wet Device connector into the receptacle, as this may damage the RF generator).
	Device, cable, or connector is damaged	Check all connections, cable, and the Device for visible damage. Replace Device.
Temperature high	Saline in Device connector	Check for presence of saline. If present, contact VNUS Customer Service. (Note: Take care never to plug a wet Device connector into the receptacle, as this may damage the RF generator).
	Temperature Set Point is set too high	Check Temperature Set Point.
Unable to activate RF Power	Temperature and/or Impedance parameter outside Functional Limits	Check Temperature and Impedance parameter values; adjust as necessary to bring parameters into Functional range.

Electromagnetic Interference (EMI)

The RF Generator might cause interference that can affect other equipment. Such interference might occur during RF Treatment Mode or during any mode that performs low power measurements, such as Measure, Body Test, or Saline Test Modes.

If interference affects other equipment in the treatment area, move the RF Generator to a different location and move the RF Generator cord and the Device away from the susceptible equipment and its cords and cables.

The RF Generator is susceptible to interference from EMI emitted by other equipment. This could result in inaccurate RF Power delivery and possible injury to the patient. Additionally, RF Treatment might halt or the unit might restart due to a non-repeating event, such as memory corruption related to electrical or radiation events, power surges, or power spikes.

Possible sources of EMI interference can include, but are not limited to, cellular phones, radio transmitters, motors, telephones, lamps and other medical equipment, such as electrosurgical products and defibrillators. Restrict the use of this equipment in the vicinity of the RF Generator.

Glossary of Terms

Advisory Limits – Limits on parameters, such as Temperature, Impedance, RF Power, Time, or a combination of these, outside of which RF Treatment is not optimal and corrective action is suggested.

Alarm Tone – The Alarm Tone sounds if the unit detects that a parameter has exceeded the Functional Limits for the connected Device.

Body Test – Performs Temperature and Impedance measurements using the Device positioned in the patient for RF Treatment.

Device – An approved VNUS RF delivery or RF powered accessory (e.g., catheter, that can be attached to the RF Generator).

Default – A value for a setting that is assigned automatically by the RF Generator. Default values remain in effect unless reconfigured in the RFG Setup or Device Setup menu.

EMI – Electromagnetic Interference.

Error Log – Description of, and RF delivery data surrounding, an error condition. This data is stored for later retrieval.

Functional Limits – Limits on parameters, such as Temperature, Impedance, RF Power, Time, or a combination of these, outside of which RF delivery halts immediately.

Impedance – Ratio of instantaneous voltage divided by instantaneous current. Both Closure*FAST* and Closure*RFS* use magnitude impedance (the magnitude of the complex Impedance vector).

Informational Tone – The Informational Tone sounds if the unit detects that a parameter is between the Advisory and Functional Limits for the connected Device.

LCD – Liquid-Crystal Display.

MMC – MultiMediaCard.

Parameter – The parameters that govern the RF Treatment algorithm—Temperature, Impedance, RF Power, and/or Time, depending on the Device.

PC – IBM®-compatible Personal Computer.

Persistent Settings – Operator-adjustable settings that retain their value when the RF Generator is turned off, such as screen brightness and tone volume settings.

POST – Power On Self Test.

Power – Real Power [heating power $= I_{RMS} * V_{RMS} * \cos\theta$] delivered to a Device.

Power Limit – Maximum RF Power that the Device can deliver.

Power Measurement – Current RF Power being delivered.

Power Set Point – The desired RF Power.

RAM – Random Access Memory.

Recoverable Error – An error condition that requires the operator to respond to an error message or make a clinical decision.

ROM – Read-Only Memory.

Real Impedance – Magnitude of the real portion of the complex Impedance vector.

RF – Radiofrequency energy.

RFC – Radiofrequency Computer.

RFG – RF Generator.

RFG2 – Model number of VNUS RF Generator.

RF Treatment – Therapeutic RF delivery.

Saline Test – Performs Temperature and Impedance measurements using saline solution.

Setting – Operator-configurable controls listed within the RFG Setup and Device Setup menus.

Temperature – Temperature, as measured at the Device point of RF delivery.

Temperature Measurement – The current Temperature.

Temperature Set Point – The desired or target Temperature.

Therapeutic RF – RF Power levels delivered by a Device that exceed 10mW average power. This term is defined to distinguish between RF Power levels used for RF Treatment and lower RF Power levels used exclusively for parameter measurement.

Unrecoverable Error – An error condition that halts the RF Generator and requires the operator to reset the RF Generator's AC Power to continue.

VNUS – VNUS® Medical Technologies, Inc.

MEDICAL EQUIPMENT MODEL RFG2
WITH RESPECT TO ELECTRICAL SHOCK,
FIRE AND MECHANICAL HAZARDS ONLY
IN ACCORDANCE WITH UL60601-1
CAN/CSA C22.2 NO.601.1
75AK

Rx ONLY

CE 0123

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